Remarks

Status of the Claims

Claims 1-28, 33-36, 42, 44, 45, 47-74, 76-79, and 86-93 are pending in this application, and subject to a Restriction Requirement. Claims 1, 36, 47, 48, 79, 86, 88, and 89 are amended herein and new claim 94 is added.

Support for the amendment of the claims can be found throughout the specification, the claims as originally filed, and at least on page 6, lines 9-14 and page 6, lines 19-29. Support for new claim 94 can be found throughout the specification and at least original claims 1 and 48, and page 6, lines 9-14 and page 6, lines 19-29.

After entry of this paper, **claims 1-28, 33-36, 42, 44, 45, 47-74, 76-79, 86 and 94 are pending** and ready for substantive examination.

Telephone Interviews

Applicants thank the Examiner for briefly discussing this case with the undersigned on February 22, and 28. The Examiner clarified the restriction requirement with respect to the number of Groups (I and II) and the nature of the restriction between SEQ ID NO:1 and SEQ ID NO:3, should the Applicant elect Group I. The Examiner also indicated that should SEQ ID NO:1 and SEQ ID NO:3 be shown to be structurally related, for example by having a high degree of sequence homology, the restriction between these sequences might be withdrawn.

Response to Restriction Requirement

Groups I and II

Claims 1-28, 33-36, 42, 44, 45, 47-74, 76-79, and 86-93 were indicated as being subject to a restriction requirement. In particular, the following Groups were designated:

Group I (claims 1-29, 33-36, 42, 44-45, 47, and 90-91): drawn to a herpes simplex virus comprising a nucleic acid encoding an antisense to the squamous cell carcinoma related oncogene and a method of expressing *in vitro* and *in vivo* a herpes simplex virus comprising a nucleic acid encoding an antisense to the squamous cell carcinoma related oncogene; and

Group II (claims 48-74, 76-79, 86-89, and 92-93): drawn to a herpes simplex virus comprising a nucleic acid encoding a short interfering ribonucleic acid (siRNA) to the squamous cell carcinoma related oncogene and a method of expressing *in vitro* and *in vivo* a herpes simplex virus comprising a nucleic acid encoding an siRNA to the squamous cell carcinoma related oncogene .

The Office action states that "Groups I-IV[1] do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features…" All of the Groups do relate to a single special technical feature, and this feature makes a contribution over the prior art. As such, all of the claims should be examined together. Applicants traverse this restriction and request that it be withdrawn in view of the arguments and amendments made herein.

Standard for Analyzing Unity of Invention

37 CFR § 1.475 requires unity of invention in a national stage application such as this; unity of invention is present when a group of inventions are "so linked as to form a single general inventive concept." [*See* 37 CFR § 1.475(a).] "A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature." [MPEP § 1893.03(d). *See also* 37 CFR § 1.475(a).]

Further, "The expression 'special technical features' shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art." [*See* 37 CFR § 1.475(a), emphasis added.]

This makes it clear that an analysis with regard to unity of invention occurs in two stages. First, is there a special technical feature shared among the claims/groups of inventions, such that they are linked to form a single inventive concept? If there is, then one asks does that special technical feature **define a contribution over the prior art** for each of the claimed inventions? If no relevant prior art is identified, then there can be no finding of lack of unity.

[1] It is believed that the erroneous reference in the current action to "Groups I-VI" is a typographical error and should actually read Groups I and II. This was verified by the Examiner in a brief telephone conference of February 22, 2007.

Applying the Standard in the Current Case

The Office has incorrectly characterized the "special technical feature" of Groups I-II as being a "herpes simplex virus comprising a nucleic acid encoding an antisense to the squamous cell carcinoma related oncogene." This mischaracterizes the claim set as a whole. Without defining a feature of **all of the claims**, the Office has not properly performed the required analysis.

The designation of a "herpes simplex virus comprising a nucleic acid encoding an antisense to the squamous cell carcinoma related oncogene" as the special technical feature mischaracterizes Applicant's invention. The special technical feature that is common to all the claims is a **herpes simplex virus wherein the herpes simplex virus genome comprises a nucleic acid capable of repressing or silencing expression of squamous cell carcinoma related oncogene (SCCRO) nucleic acid or polypeptide**. To more clearly illustrate this, new claim 94 was been added and recites a "**herpes simplex virus wherein the herpes simplex virus genome comprises a nucleic acid capable of repressing or silencing expression of squamous cell carcinoma related oncogene (SCCRO) nucleic acid or polypeptide.**" The pending claims have been amended to depend either directly or indirectly from claim 94.

Groups I and II are linked to form a single general inventive concept. The invention as claimed relates to a "**herpes simplex virus wherein the herpes simplex virus genome comprises a nucleic acid capable of repressing or silencing expression of squamous cell carcinoma related oncogene (SCCRO) nucleic acid or polypeptide**." This special technical feature is shared among all of the claims. The special technical feature of is *explicitly* recited (directly or indirectly) in all claims as amended. This special technical feature defines a contribution over the prior art because no reference has been cited in the Restriction Requirement. Since the Office has provided neither allegation nor evidence that the concept of a "**herpes simplex virus wherein the herpes simplex virus genome comprises a nucleic acid capable of repressing or silencing expression of squamous cell carcinoma related oncogene (SCCRO) nucleic acid or polypeptide**" is disclosed or rendered obvious by the prior art, this feature clearly constitutes an appropriate "corresponding special technical feature" sufficient for

the fulfillment of the unity of invention requirement. [*See* 37 CFR § 1.475(a); MPEP § 1893.03(d).]

In summary, **as required by 1.475**, the claims pending in the application have unity of invention because they are directed "to a group of inventions so linked as to form a single general inventive concept" because "there is a technical relationship among [the] inventions involving one . . . corresponding technical feature[]" – a "**herpes simplex virus wherein the herpes simplex virus genome comprises a nucleic acid capable of repressing or silencing expression of squamous cell carcinoma related oncogene (SCCRO) nucleic acid or polypeptide**" – and this special technical feature "define[s] a contribution . . . over the prior art." Applicants note for the record that unity was found in the International Application that forms the basis of the current application.

Since unity of invention exists between the Groups in the present application (once a correct special technical feature is defined), restriction of the claims is inappropriate. Applicants request that the restriction be withdrawn, that Groups I and II be rejoined and all of the claims be examined.

SEQ ID NO:1 and SEQ ID NO:3

The Restriction Requirement also required that should Group I be elected, an additional election must be made between SEQ ID NO:1 and SEQ ID NO:3. Applicants traverse this restriction and request that it be withdrawn. The Restriction Requirement alleges that "SEQ ID NO:1 and SEQ ID NO:3 are chemically distinct inventions under PCT Rule 13.2 because the two sequences do not share a significantly identical structure". In the brief telephone conference between the undersigned and the Examiner on February 28, 2007, the possibility of overcoming this restriction was discussed. The Examiner indicated that the restriction might be withdrawn if it could be shown that the two sequences share a high degree of sequence identity. As stated in M.P.E.P. 1850 (III)(B) "the requirement of a technical interrelationship and the same or corresponding special technical features as defined in PCT Rule 13.2, shall be considered to be met when the alternatives are of a similar nature". This section also states that:

"chemical compounds shall be regarded as being of a similar nature where the following criteria are fulfilled:

(A) All alternatives have a common property or activity; and

(B) (1) A common structure is present, i.e., a significant structural element is shared by all of the alternatives …"

SEQ ID NO:1 and SEQ ID NO:3 fulfill the above criteria and thus restriction is improper. SEQ ID NO:1 and SEQ ID NO:3 have a common property and activity, namely they are antisense to SCCRO and are capable of repressing or silencing expression of squamous cell carcinoma SCCRO nucleic acid or polypeptide. SEQ ID NO:1 and SEQ ID NO:3 also share a common structure (*i.e.* sequence). Submitted herewith as Exhibit A is a sequence alignment generated between SEQ ID NO:1 and SEQ ID NO:3. As is shown in Exhibit A, SEQ ID NO:1 and SEQ ID NO:3 share 92% identity across the entire sequence. This significant sequence homology clearly indicates that SEQ ID NO:1 and SEQ ID NO:3 share a common structure. In light of the above arguments, Applicants request that the restriction between SEQ ID NO:1 and SEQ NO:3 be withdrawn.

Election

Solely to comply with 37 CFR §1.499, Applicants hereby provisionally elect Examiner's Group I (defined in the Office action as corresponding to claims **1-29, 33-36, 42, 44-45, 47, and 90-91**. In addition, solely to comply with 37 CFR §1.499, Applicants hereby provisionally elect SEQ ID NO:1. Should the Office recharacterize SEQ ID NO:1 and SEQ ID NO:3 as species, Applicants provisionally elect SEQ ID NO:1 for initial examination with the understanding that the non-elected species will be rejoined when a generic claim is found allowable.

In accord with 37 CFR §1.143, Applicant specifically reserves the right to petition to have the appropriateness of the finding of lack of unity/restriction requirement reconsidered, if it is maintained in spite of this response.

Conclusion

Applicants believe that the present claims are in condition for substantive examination, and such action is requested. The Examiner is invited to call the undersigned if the Examiner believes that a telephone interview would facilitate substantive examination of this application.

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